

**Custom Fabricated Adjustable
Bi-Flanged Fistula Prosthesis :
Clinical Experience**

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PATIENT #1

INITIALS DA

AGE 57

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Total laryngectomy, left modified neck dissection, right modified neck dissection (5/19/11)
- > Tobacco use

FISTULA INFORMATION:

SIZE : 10mm
SHAPE : Round
TYPE : High pharyngocutaneous
LOCATION : Submental region midline

PREVIOUS ATTEMPT TO HEAL:
Local rotational flap (07/05/11)

DIAGNOSIS:

- > Post radiation failure left true cord and anterior right cord (6/20/10).
- > Recurrent laryngeal cancer (04/2011).

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : NP *
STEM : Single
DURATION OF USE : 28 days
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Transoral retrograde insertion.
Insertion: 8/1/11; Removal: 8/29/11

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: None
SIZE AND APPEARANCE OF FISTULA:
Fistula gradually closed around stem of fistula prosthesis to approximately 2 mm in 28 days.
CLOSURE OF FISTULA:
Complete spontaneous residual 2 mm closure achieved approximately 2 -3 weeks post prosthesis removal. Small round bandage in place during this time period.

* Information not provided by clinician

PATIENT #2

INITIALS YB

AGE 75

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Hypothyroidism
- > Pharyngectomy, esophagectomy, gastric pull up (10/2010)
- > Severe gastric reflux

FISTULA INFORMATION:

SIZE : 8mm
SHAPE : Single
TYPE : Pharyngocutaneous
LOCATION : 5cm above and right of tracheostoma

PREVIOUS ATTEMPT TO HEAL:
Pharyngocutaneous flap (11/04/2010)

DIAGNOSIS:

- > Laryngeal cancer Total laryngectomy (1979)
- > Cervical esophageal cancer (2010)

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 18mm
STEM : Single
DURATION OF USE : 47 days
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Following Q-tip applicator insertion to confirm fistula tract direction, the inner flange on the prosthesis was inserted without anesthesia in the office. Insertion: 11/24/10; Removal: 1/10/11

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Yeast colonization noted on the surface of the silicone flanges at time of prosthesis removal

SIZE AND APPEARANCE OF FISTULA:

Fistula diameter reduced from 8 mm to 2 mm. The prosthesis eliminated leakage throughout the period of use.

CLOSURE OF FISTULA:

The residual 2 mm opening that was present at the time of prosthesis removal quickly closed without further medical management

* Information not provided by clinician

PATIENT #3

INITIALS DK

AGE 72

SEX F

**PRECEDING
COMPLICATIONS:**

- > *Radiation therapy*
- > *Malnutrition*
- > *Hypothyroidism*
- > *Total laryngectomy (2000)*

FISTULA INFORMATION:

SIZE : *12mm*
SHAPE : *Round*
TYPE : *Pharyngocutaneous*
LOCATION : *Right neck*

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

Laryngeal cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *38mm*
STEM : *Single + Double*
DURATION OF USE : *4+ months*
ADDITIONAL INFO : *NP **

INSERTION PROCEDURE:
Retrograde insertion

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
Fungal colonization noted on both anterior and posterior flanges causing warping of the flanges requiring replacement after 2 months of use

SIZE AND APPEARANCE OF FISTULA:
No overt change, however leakage controlled with fistula prosthesis use

CLOSURE OF FISTULA:
*NP **

* Information not provided by clinician

PATIENT #4

INITIALS VE

AGE 64

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Hypothyroidism
- > Laryngopharyngectomy with PM flap reconstruction (11/25/03)
- > Right-side carotid blow out (12/16/03)
- > Wound dehiscence treated with right DP flap (1/27/10)
- > Right latissimus flap reconstruction (4/22/04)
- > Gastric reflux
- > Wound dehiscence treated with left PM flap (12/12/03)

FISTULA INFORMATION:

SIZE : 10x20mm
SHAPE : Oval
TYPE : Tracheoesophageal
LOCATION : 2-2.5cm posterior tracheal wall below rim of tracheostoma

PREVIOUS ATTEMPT TO HEAL:

See surgical procedure preceding fistula

DIAGNOSIS:

Laryngeal Cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 20x26mm
STEM : Single
DURATION OF USE : 5 days and 4 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

The inner flange was tightly folded bedside insertion and half with a curved hemostat office insertion trans fistula, Insertion from the outside folded by outer flange assembly and adjustment. Prosthesis #1: Insertion: 4/30/04; Removal: 5/1/04; Prosthesis #2: Removal: 8/30/04.

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Mild yeast colonization on the flange surface noted upon removal.

SIZE AND APPEARANCE OF FISTULA:

Original 10 x 20 mm fistula closed down around the stem of the prosthesis to be a 3mm round fistula at time of prosthesis removal after 4 months continuous use. Fistula prosthesis successfully eliminated leakage/aspiration during its 4 mos.

CLOSURE OF FISTULA:

The prosthesis was removed and the residual approx. 3mm opening prolapsed/closed over the following few days.

* Information not provided by clinician

PATIENT #5

INITIALS BF

AGE 75

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Hypothyroidism
- > Laryngopharyngectomy with a PM flap reconstruction (1983)
- > Recurrent squamous cell carcinoma with total pharyngectomy, left neck dissection, left radial free flap (12/3/08)

FISTULA INFORMATION:

SIZE : 10x8mm
SHAPE : Triangular
TYPE : Pharyngocutaneous
LOCATION : Right-side in submental region

PREVIOUS ATTEMPT TO HEAL:

Latissimus dorsi pedical flap to close wound breakdown and pharyngocutaneous fistula (1/28/2009)

DIAGNOSIS:

T2 M0 N1 supraglottic cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 38mm and 44mm
STEM : Single
DURATION OF USE : 11 days to 4 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Trans fistula from the outside with the flange folded and held in a hemostat. Always inserted without anesthesia as an office procedure; Prosthesis #1: 3/25/09-7/2/09; Prosthesis #2: 7/2/09-8/20/09; Prosthesis #3: 8/20/09-11/2/09; Prosthesis #4: 11/2/09-12/17/09; Prosthesis #5: 12/17/09-12/28/09; Prosthesis #6: 12/28/09-1/26/10; Prosthesis #7: 1/26/10-3/2/10; Prosthesis #8: 3/2/10-8/16/10; Prosthesis #9-8/6/10-11/27/10; Prosthesis #10: 11/27/10-expired 3/2011.

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

All removed prostheses showed mild-moderate yeast colonization of flange. Prosthesis #3 was dislodged outwardly on hard coughing. Prosthesis #8 came apart.

SIZE AND APPEARANCE OF FISTULA:

3/25/09: Original fistula; 1 cm x 8 mm (see photos). 8/20/09: Slightly smaller. 8/6/10: Almost complete granulation closure around the prosthesis' stem.

CLOSURE OF FISTULA:

NA - Patient expired 03/2011.

PATIENT #6

INITIALS MM

AGE 87

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Malnutrition
- > Hypothyroidism
- > Total laryngectomy

FISTULA INFORMATION:

SIZE : 10mm
SHAPE : Oval
TYPE : Pharyngocutaneous
LOCATION : Left neck ~1cm superior/lateral to stoma

PREVIOUS ATTEMPT TO HEAL:
Primary closure/local flaps

DIAGNOSIS:

Laryngeal cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : NP *
STEM : Single
DURATION OF USE : 24+ months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Inner flange folded then inserted into fistula

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
Patient had prosthesis fall out several times due to patient's coughing. Patient pulled prosthesis out during sleep.

SIZE AND APPEARANCE OF FISTULA:
Fistula narrowed to < 3mm in size and still using prosthesis.

CLOSURE OF FISTULA:
Still open. Patient not interested in removing fistula prosthesis to see if it will close spontaneously at this point.

* Information not provided by clinician

PATIENT #7

INITIALS *DH*

AGE *77*

SEX *M*

**PRECEDING
COMPLICATIONS:**

> *Total laryngectomy with partial
pharyngectomy (2000)*
> *Esophageal stent (2002)*

FISTULA INFORMATION:

SIZE : *20mm*
SHAPE : *Oval*
TYPE : *NP **
LOCATION : *Tracheoesophageal*
PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

Laryngeal Cancer ; pharyngeal stenosis

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *38mm*
STEM : *Single*
DURATION OF USE : *10+ months*
ADDITIONAL INFO : *NP **

INSERTION PROCEDURE:

*Esophageal flange folded and tucked into
fistula with hemostats , tracheal flange
tightened down stem*

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

*Fungal colonization noted on esophageal
flange after 6 months of use. Prosthesis dis-
lodged twice following initial 6 months of use,
this occurred because patient accidentally pulled
device out.*

SIZE AND APPEARANCE OF FISTULA:

*No change in size or shape but aspiration of
secretions controlled with fistula prosthesis use*

CLOSURE OF FISTULA:

NA

PATIENT #8

INITIALS SS

AGE 44

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Split lip/mandible
- > Subtotal glossectomy right modified neck dissection
- > Right pectoralis major flap, soft palatectomy
- > Tracheotomy

FISTULA INFORMATION:

SIZE : *Approximately 2mm*
SHAPE : *Round*
TYPE : *NP **
LOCATION : *Orocutaneous/Submental*

PREVIOUS ATTEMPT TO HEAL:
Cauterized silver nitrate

DIAGNOSIS:

Locally advanced squamous cell carcinoma of the right lateral tongue and tongue base

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *25mm*
STEM : *Single*
DURATION OF USE : *18 months*
ADDITIONAL INFO : *NP **

INSERTION PROCEDURE:

Suture passed though fistula into the cavity and tied to stem of prosthesis which was inserted in retrograde fashion. Anterior flange threaded down stem

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Some skin erosion around anterior flange edge. A larger (~30 mm) softer anterior flange placed which resolved the issue. Dislodged anterior flange

SIZE AND APPEARANCE OF FISTULA:

No change in size but leakage controlled

CLOSURE OF FISTULA:

NA

* Information not provided by clinician

PATIENT #9

INITIALS RB

AGE 71

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Left endoscopic ethmoidectomy with biopsy and partial removal of nasal and ethmoid mass (8/19/2011)
- > Extra dural approach and resection of left maxilla, ethmoid, sphenoid and frontal sinuses, resection of left periorbital septal flap suspension of orbit pericranial flap split thickness skin graft to the orbit and skull base 80cm squared (12/28/2011)

FISTULA INFORMATION:

SIZE : 1x2mm
SHAPE : Oval
TYPE : NP *
LOCATION : Nasal cutaneous/Left inferior orbital rim medially

PREVIOUS ATTEMPT TO HEAL:
Medial forehead flap

DIAGNOSIS:

Sinonasal carcinoma

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 5mm
STEM : Single
DURATION OF USE : 2 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Anterograde insertion with folded flange

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
Fistula expanded and device was dislodged
SIZE AND APPEARANCE OF FISTULA:
Fistula expanded during use
CLOSURE OF FISTULA:
Closed surgically

* Information not provided by clinician

PATIENT #10

INITIALS SG

AGE 83

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Hypothyroidism
- > Neck dissections
- > Enlarging tracheoesophageal puncture site

FISTULA INFORMATION:

SIZE : 10x10mm
SHAPE : Oval
TYPE : Enlarged tracheal-esophageal puncture (TEP)
LOCATION : TEP

PREVIOUS ATTEMPT TO HEAL: None

DIAGNOSIS:

- > H/O laryngeal cancer
- > Pharyngocutaneous fistula
- > Metastatic cancer to lungs, liver and bone.

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 20mm
STEM : Single
DURATION OF USE : 8 days
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
General anesthesia (9/29/11)

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
Insertion went well. Prosthesis was dislodged at nursing home 8 days later.

SIZE AND APPEARANCE OF FISTULA:
Same

CLOSURE OF FISTULA:
Fistula closed surgically 11/11/11

* Information not provided by clinician

PATIENT #11

INITIALS HJ

AGE 60

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy (2006 & 2008)
- > Chemotherapy (2006)
- > Hypothyroidism
- > Laryngopharyngectomy, tubed pectoralis flap reconstruction, bilateral neck dissection (2/26/08)
- > Gastric reflux

FISTULA INFORMATION:

SIZE : 6mm & 12x6mm
SHAPE : Round & Oblong
TYPE : Both Fistulas
LOCATION : Midline 1-2cm above tracheostoma

PREVIOUS ATTEMPT TO HEAL:

Local rotational flap (10/30/2008); opened again (11/08/2008) and enlarged (12/1/2008). No prosthesis placement from 11/8/2008 to 12/1/2008

DIAGNOSIS:

Pulmonary cancer. (2007) Recurrent pulmonary cancer. (2008) Lt parapharyngeal recurrence. (7/08) Left tonsillar cancer treated with chemo/ radiation (12/06). Recurrence in larynx (2/08).

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 16mm & 20x16mm
STEM : Single & Double
DURATION OF USE : 3 months & 2 months & 5 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Transcutaneous insertion with a hemostat holding the compressed folded flange

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

No adverse events with exception of spontaneous fluctuations in fistula size / shape. Moderate yeast colonization noted on flange surfaces of the fistula prostheses

SIZE AND APPEARANCE OF FISTULA:

Fistula at first seemed to reduce in size and then enlarge

CLOSURE OF FISTULA:

Fistula never resolved. Open with packing at date patient expired.

* Information not provided by clinician

PATIENT #12

INITIALS HL

AGE 84

SEX M

**PRECEDING
COMPLICATIONS:**

- > Completion thyroidectomy, neck dissection, and tracheal resection
- > Tracheostoma created during surgery which narrowed and not closed

FISTULA INFORMATION:

SIZE : 4mm
SHAPE : Round
TYPE : Tracheocutaneous
LOCATION : From resection/midline above sternal notch

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

Recurrent thyroid cancer with tracheal invasion

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 20mm
STEM : Single
DURATION OF USE : 10 weeks
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Flange folded and inserted in anterograde fashion

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: None
SIZE AND APPEARANCE OF FISTULA:
Narrowed to 1 mm prior to removal for tracheotomy
CLOSURE OF FISTULA:
Patient was found to have recurrent cancer in the trachea necessitating tracheostomy at fistula site

* Information not provided by clinician

PATIENT #13

INITIALS SK

AGE 51

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Total laryngectomy, bilateral neck dissection, right PM flap closure (10/25/10)
- > Steroid use (3/2010-6/2010)
- > Gastric Reflux

FISTULA INFORMATION:

SIZE : 20mm & NP *
SHAPE : Slit & NP *
TYPE : NP * & NP *
LOCATION : Submental region right side & 2:00 low

PREVIOUS ATTEMPT TO HEAL:

None

DIAGNOSIS:

Grade 2, T1, N0, M0 squamous cell cancer glottic larynx (9/2006); recurrent squamous cell cancer left true vocal cord (11/2006); large recurrence left and right cord, base of epiglottis (8/2010)

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 20mm
STEM : Single
DURATION OF USE : 2 days
ADDITIONAL INFO : Both 20mm units

INSERTION PROCEDURE:

Transcutaneous insertion through the fistula from the outside. Inner flange tightly folded in a hemostat.

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

None. Both (fistula) prostheses were removed. Tissues very necrotic. Unsuccessful prosthesis application.

SIZE AND APPEARANCE OF FISTULA:

Prosthesis could not seal fistula leakage. Prosthesis removed after 48 hrs.

CLOSURE OF FISTULA:

Both fistulas continued to enlarge substantially. Salivary bypass tube and g- tube placed

PATIENT #14

INITIALS OM

AGE 54

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Hypothyroidism
- > Total laryngectomy, alt flap
- > Drug use – “crack”

FISTULA INFORMATION:

SIZE : 6mm
SHAPE : Tubular
TYPE : PCF
LOCATION : Left Neck

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

Recurrent laryngeal cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 10mm
STEM : Single
DURATION OF USE : 3 weeks
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

OR placement, threaded catheter through from inside through outside and made snug

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Insertion - no adverse events. Some difficulty threading stem through tract because of tract deviation. Use - no adverse events. Removal - No adverse. Came out very easily.

SIZE AND APPEARANCE OF FISTULA:

Fistula became much smaller and with less secretions, less erythema.

CLOSURE OF FISTULA:

Fistula device closed PCF down ~ 95%. Once removed, after tissue healed. Once removed, residual fistula tract was packed which closed within 1 week. Successful use.

PATIENT #15

INITIALS SN

AGE 36

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Partial laryngopharyngectomy, bilateral mod.
Radical neck dissection level II-III, CP myotomy,
TEP 1°, immediate pectoralis major muscle flap of
pharynx (11/28/11)
- > HX random vomiting, esophageal stenosis from
chemo xRT

FISTULA INFORMATION:

SIZE : 6-7mm
SHAPE : Round
TYPE : TE
LOCATION : Left neck outside of stoma

PREVIOUS ATTEMPT TO HEAL:

1 free flap for neck fistula outside stoma, 3 for
TE fistula

DIAGNOSIS:

scc larynx (supraglottis) s/p chemoradiation tx
prior to TL.

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 20mm
STEM : Single
DURATION OF USE : 4 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

5/24/12- Folded flanged with hemostats. Placed
easily without obvious tissue degradation

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

No adverse events with placement, use or removal. Patient
was able to eat for 4 months regular diet (gained weight for
1st time). She reported increased episodes of vomiting. After
4 months the prosthesis fell out with an episode of vomiting. It
was yellowed and slightly curled on esophageal side. This was
the left neck fistula. No infection or colonization of bacteria/
fungal issues. Acidic discoloration from vomiting.

SIZE AND APPEARANCE OF FISTULA:

Baseline appearances - see attached photo. Patient vomited
and free flap on left neck deteriorated so no post fistula com-
parison could be made. Fistula size and appearance remained
consistent, slightly larger with vomiting, but tissue remained
with same thickness and color for 4 months during f/u visits -
see final photo of free flap repair.

CLOSURE OF FISTULA:

Free flap reconstruction of neck fistula healed well with no
further need for fistula device.

* Information not provided by clinician

PATIENT #16

INITIALS *UO*

AGE *60*

SEX *F*

**PRECEDING
COMPLICATIONS:**

- > *Radiation therapy*
- > *Diabetes*
- > *Laryngectomy*
- > *Alcoholism*

FISTULA INFORMATION:

SIZE : *6x5mm*
SHAPE : *Elliptical*
TYPE : *Pharyngocutaneous*
LOCATION : *Supra stomal*

PREVIOUS ATTEMPT TO HEAL:
Local flap, pectoralis flap

DIAGNOSIS:

Supraglottis squamous cell carcinoma

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *NP **
STEM : *Single*
DURATION OF USE : *Few months*
ADDITIONAL INFO : *Custom fabricated fistula
prosthesis*

INSERTION PROCEDURE:
Placed in office setting

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: *None*
SIZE AND APPEARANCE OF FISTULA: *NP **
CLOSURE OF FISTULA: *Pectoralis flap*

* Information not provided by clinician

PATIENT #17

INITIALS SD

AGE 66

SEX M

**PRECEDING
COMPLICATIONS:**

- > *Radiation therapy*
- > *Chemotherapy*
- > *Hypothyroidism*
- > *Total laryngectomy, bilateral neck dissections, TEP*

FISTULA INFORMATION:

SIZE : 4mm
SHAPE : Round
TYPE : NP *
LOCATION : Right supra lateral neopharynx

PREVIOUS ATTEMPT TO HEAL:
Local tissue rearrangement

DIAGNOSIS:

Laryngeal Cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 6mm
STEM : Single
DURATION OF USE : 8 weeks
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Direct visualization

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: *None*
SIZE AND APPEARANCE OF FISTULA:
Fistula became smaller after insertion
CLOSURE OF FISTULA:
Local flap closure

* Information not provided by clinician

PATIENT #18

INITIALS SH

AGE 69

SEX F

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Total laryngectomy for salvage after failed chemo radiation therapy

FISTULA INFORMATION:

SIZE : 6mm & 3mm
SHAPE : Circular & Circular
TYPE : NP *
LOCATION : Enlarged TEP & Right superior neopharynx

PREVIOUS ATTEMPT TO HEAL:
Local tissue rearrangement

DIAGNOSIS:

Laryngeal cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 8mm & 5mm
STEM : Single
DURATION OF USE : 3 weeks & still in use
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Direct placement (both prostheses)

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
1st Prosthesis: For TEP fistula, insertion was difficult due to unusual size and shape of the fistula. The prosthesis enlarged the TEP site further and therefore was removed.
SIZE AND APPEARANCE OF FISTULA:
1st Prosthesis: TEP site was larger
CLOSURE OF FISTULA:
1st Prosthesis: Unable to close the fistula (TEP);
2nd Prosthesis: Still in Use

* Information not provided by clinician

PATIENT #19

INITIALS PS

AGE 72

SEX M

**PRECEDING
COMPLICATIONS:**

- > *Radiation therapy*
- > *Chemotherapy*
- > *Malnutrition*
- > *Hypothyroidism*
- > *Salvage total laryngectomy*

FISTULA INFORMATION:

SIZE : 3mm
SHAPE : Oval
TYPE : High pharyngocutaneous
LOCATION : Suprastomal/Apron flap

PREVIOUS ATTEMPT TO HEAL:
Silver nitrate cauterization

DIAGNOSIS:

Supraglottic CA/failed chemo radiation

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 10mm
STEM : Single
DURATION OF USE : 3 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Placed in operating room using retrograde catheter insertion/ securing stem to catheter and pulling anterograde separate disc secured

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

*NP *; No colonization noted at explanation*

SIZE AND APPEARANCE OF FISTULA:

Fistula size diminished from 3 mm to the diameter of the prosthesis stem

CLOSURE OF FISTULA:

Patient developed 2nd fistula site surgeon decided to proceed with pectoralis muscle flap closure

PATIENT #20

INITIALS RM

AGE 57

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Malnutrition
- > Hypothyroidism
- > Left composite resection with microvascular free flap fibula reconstruction

FISTULA INFORMATION:

SIZE : 5mm
SHAPE : Ellipse
TYPE : NP *
LOCATION : Left floor of mouth orocutaneous

PREVIOUS ATTEMPT TO HEAL:

2 failed free flaps, pectoralis flap, latissimus dorsi flap

DIAGNOSIS:

1. Oral/tongue cancer surgery post op XRT (2008)
2. Osteonecrosis left mandible (2011)

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 15mm
STEM : Single
DURATION OF USE : 8 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Direct placement under anesthesia

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

NP *: No adverse colonization on prosthesis noted

SIZE AND APPEARANCE OF FISTULA:

5mm > size of prosthesis stem. No leakage around stem

CLOSURE OF FISTULA:

Patient died of disease

PATIENT #21

INITIALS HP

AGE 80

SEX M

**PRECEDING
COMPLICATIONS:**

- > Radiation therapy
- > Chemotherapy
- > Hypothyroidism
- > Total laryngectomy, bilateral neck dissect (5/2007)
- > Severe esophageal stenosis with multiple dilations and eventual complete esophageal stenosis

FISTULA INFORMATION:

SIZE : 6mm
SHAPE : Round
TYPE : Pharyngocutaneous
LOCATION : Anterior neck right of center

PREVIOUS ATTEMPT TO HEAL:

Multiple attempts including rotational flaps

DIAGNOSIS:

CA larynx

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 12mm
STEM : Single
DURATION OF USE : 3 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Flange folded and inserted with small curved forceps

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Mild candida colonization on the esophageal flange

SIZE AND APPEARANCE OF FISTULA:

The overall size of the fistula decreased to approx. 3mm prior to successful surgical closure.

CLOSURE OF FISTULA:

De-epithelialization of the pharyngocutaneous fistula tract with sutured closure. Tract was quite small and had decreased in diameter since fistula prosthesis placement.

* Information not provided by clinician

PATIENT #22

INITIALS LH

AGE 83

SEX F

**PRECEDING
COMPLICATIONS:**

- > *Radiation therapy*
- > *Hypothyroidism*
- > *Total laryngopharyngectomy*

FISTULA INFORMATION:

SIZE : 9mm
SHAPE : Oval
TYPE : NP *
LOCATION : TE

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

*NP **

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : NP *
STEM : Single
DURATION OF USE : 4-8 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:
Placed in the OR transtracheal

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:
With time flange will curl. Fistula flange seal was compromised until device was replaced
SIZE AND APPEARANCE OF FISTULA:
Slight increase in fistula size over time. Approximately 5 prosthesis placements without complication
CLOSURE OF FISTULA:
*NP **

* Information not provided by clinician

PATIENT #23

INITIALS MT

AGE 61

SEX M

**PRECEDING
COMPLICATIONS:**

> *Radiation therapy*
> *Hypothyroidism*
> *Total laryngectomy*

FISTULA INFORMATION:

SIZE : *8mm*
SHAPE : *Oval*
TYPE : *NP **
LOCATION : *TE*

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

Larynx cancer

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *NP **
STEM : *Single*
DURATION OF USE : *6 months*
ADDITIONAL INFO : *NP **

INSERTION PROCEDURE:
Transtracheal placement in OR

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: *None*
SIZE AND APPEARANCE OF FISTULA:
*NP **
CLOSURE OF FISTULA:
*NP **

* Information not provided by clinician

PATIENT #24

INITIALS LR

AGE 46

SEX M

**PRECEDING
COMPLICATIONS:**

> Radiation therapy
> Chemotherapy
> Composite resection including mandible
FOM, tongue, right neck dissection, PM flap
reconstruction, mandibular reconstruction
with plate, limited pharyngectomy,
tracheostomy (1/26/12)

FISTULA INFORMATION:

SIZE : 15mm
SHAPE : Oblong
TYPE : NP *
LOCATION : Orocutaneous

PREVIOUS ATTEMPT TO HEAL:
None

DIAGNOSIS:

CA/oral/tongue

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : 22mm
STEM : Single
DURATION OF USE : 4 months
ADDITIONAL INFO : NP *

INSERTION PROCEDURE:

Inserted with curved forceps after folding

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS:

Some minimal candida colonization oral
portion of stent

SIZE AND APPEARANCE OF FISTULA:

The fistula continued to demonstrate mild
increase in size secondary to continued
osteoradionecrosis

CLOSURE OF FISTULA:

Closed 7/18/13 with right rectus
myocutaneous free flap, adjacent tissue
transfer, right osteocutaneous fibula free flap.
Note: At the time of fistula prosthesis place-
ment patient was relying on total oral intake
for hydration/nutrition with significant leakage
through fistula. Fistula prosthesis completely
resolved the fistula leakage.

* Information not provided by clinician

PATIENT #25

INITIALS NP *

AGE NP *

SEX F

**PRECEDING
COMPLICATIONS:**

*NP **

FISTULA INFORMATION:

SIZE : *NP **
SHAPE : *NP **
TYPE : *Large post op*
LOCATION : *TEP*

PREVIOUS ATTEMPT TO HEAL:
*NP **

DIAGNOSIS:

*NP **

**FISTULA PROSTHESIS
INFORMATION:**

SIZE : *NP **
STEM : *NP **
DURATION OF USE : *NP **
ADDITIONAL INFO : *NP **

INSERTION PROCEDURE:
At bedside with topical anesthesia.

**FISTULA PROSTHESIS
OUTCOME:**

ADVERSE EVENTS: *NP **
SIZE AND APPEARANCE OF FISTULA:
The prosthesis fit snugly and was more effective in reducing, and virtually eliminating contamination of the trachea.
CLOSURE OF FISTULA:
Surgical Closure

SUMMARY OF RESULTS

The patient population consisted of 15 males and 10 females ranging in age from 36 to 87 years. Outcome data is below in Tables 1, 2, and 3.

Table 1

Control or elimination of salivary leakage with a custom-fabricated fistula prosthesis (by patient, n=25)

YES	21 (84%)
NO	3 (12%)
Unclear from data provided	1 (4%)

Table 2

Change in fistula size or condition during fistula prosthesis use (by patient, n=25)

Smaller	11 (44%)
Larger	6 (24%)
Unchanged	6 (24%)
Unclear from data provided	2 (8%)

SUMMARY OF RESULTS - continued

Table 3
Post-surgical adverse events reported with the custom-fabricated fistula prosthesis (by patient, n=25)

No Adverse Events	9 (36%)
No Information	4 (16%)
Prosthesis dislodged ^{1,2,3,4}	5 (20%)
Necrotic tissues	1 (4%)
Prosthesis came apart ¹	1 (4%)
Curled flange/seal compromised	1 (4%)
Enlarged TEP site	1 (4%)
Fungal colonization on flanges causing warping and resulting in removal	1 (4%)
Peri-fistula stoma fungal infection ²	1 (4%)
Skin erosion	1 (4%)
Spontaneous fluctuaion in fistula size/shape	1 (4%)
Increased vomiting ³	1 (4%)
Yeast colonization on surface of prosthesis at removal	9 (36%)
No yeast colonization noted at removal	10 (40%)
No information regarding yeast colonization at removal	6 (24%)

Notes:

- 1 - 1 // Patient had a prosthesis that dislodged and came apart
- 2 - 1 // Patient had a prosthesis that dislodged and there was a peri-fistula stomal fungal infection
- 3 - 1 // Patient had a prosthesis that dislodged and experienced increased vomiting
- 4 - 1 // Patient had a prosthesis that dislodged and experienced skin erosion

DISCUSSION and CONCLUSION

The clinical experience obtained from 25 patients treated with a custom-fabricated bi-flanged fistula prosthesis, manufactured from a commercially available, medical grade silicone with a single or double stem and flanges sized to the needs of the patient, demonstrates that such a device provides a safe and effective alternative for managing salivary fistulas. The majority of the patients treated using this modality are able to control or eliminate salivary leakage in the absence of any serious adverse events. These data provide compelling evidence to support clearance of 510(k) K130736 for the Blom-Singer® Adjustable Bi-Flanged Fistula Prosthesis.