Intact® Breast Lesion Excision System (BLES) Product Specifications

Introduction:

The ***Intact*** BLES captures breast tissue for histological review, using RF energy. The ***Intact*** BLES is uniquely able to deliver a sample with intact architecture and clear margins around the area of interest, from a swift in-office procedure.

The system can be operated from buttons on the handle, or using a foot pedal, to suit physician preference. Clear icons on both the handle and controller light up to show the progress of the procedure.

Vacuum assistance:

A conventional vacuum source or smoke evacuator must be attached to the end of the handle to remove gases or liquids that are collected at the tip of the wand during the procedure.

Imaging:

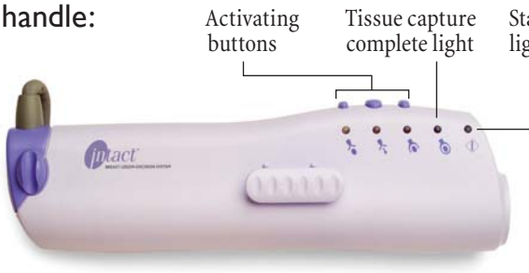
The ***Intact*** BLES can be used with stereotactic or ultrasound image guidance.

Energy requirements:

Uses any standard grounded 120 V outlet.

System components:

Intact handle:
(reusable)



Ergonomic grip

Overall Length: 8.75" (22.2cm)

Intact wand:
(sterile, single-use)

Overall Length: 13.2" (33.5cm)

Shaft Dimensions:
0.26" (6.6mm) dia. x 4.5" (11.4cm)

Intact system:

Control module

Procedure progress icons

Patient return connector

Vacuum assist module

Generates RF energy at a preset frequency of 340 kHz ± 5%

Two insulated leads operate the precursor and tissue capture basket

Dimensions:
18.25" W x 40" H x 26" D
(46.4 x 101.6 x 66 cm)

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New *Intact*® *Advance* Wand:

The size of an 8 gauge vacuum-assisted core needle biopsy device, the ***Intact*** *Advance* features a precision cutting tip, making tissue capture simpler and easier. Other advantages include:

- The need for speculum (skin spreaders) is eliminated
- Operation requires up to one-third fewer steps
- Thermal artifact is virtually eliminated
- Less space is needed—ideal for use with upright stereotactic systems or in tight quarters

Specimen Capture:

Intact *RF Precursor* ***Intact*** *Advance*

Capture basket—Five small RF-enabled wires deploy from the wand to circumscribe the lesion. As they proceed, they draw out five supporting elements which support and cradle the sample for withdrawal.

Specimen Sizes:

Sample Nominal Diameter	**10mm***	**12mm**	**15mm**	**20mm**
Average Specimen Length	13mm	17mm	18mm	18mm
Length†	17.9mm	20.2mm	22.0mm	24.5mm

* Available with RF precursor design only.

†Due to variations in tissue density and composition, there are variances in specimen size, based on Intact Medical test data. Actual basket lengths will be less than the upper limits of the above specified ranges. These specified upper limits are conservative, upon which margin calculations should be based.