EnCor EnSpire® and EnCor Ultra™ Breast Biopsy Systems

Perfect Partners
For you and your practice

INSPIRED SOLUTIONS
The EnCor® Breast Biopsy System cuts like a knife.
Jason Hechtman, M.D., F.A.C.S.

EnCor Enspire® and EnCor Ultra™ Breast Biopsy Systems
Perfect for you and your practice.

Built upon the powerful EnCor® Breast Biopsy System platform, today’s vacuum-assisted breast (VAB) biopsy products from Bard are designed to transform the biopsy experience, offering you:

- The right choice for clinical performance, regardless of modality.
- The flexibility and convenience your practice demands.
- The confidence that comes from working with Bard.

A proven platform designed for control, confidence and comfort.

- Ergonomic, **lightweight handpiece** fits easily in your hand for improved maneuverability and comfort.
- Multiple samples from a **single insertion** improves procedural efficiency and accuracy.
- **Sharp tip** reduces drag and discomfort, increases control – especially through dense tissue.
- Choice of **12G, 10G and 7G needles** offers clinical flexibility.

Samples up to 150% larger than other systems in simulated use testing.†
The EnCor® Breast Biopsy Systems produce large, quality samples, contributing to a more accurate and confident diagnosis.

Percentage Greater Tissue Mass with Comparable EnCor® Probe

<table>
<thead>
<tr>
<th>Needle Size</th>
<th>Tissue Mass Difference (Approximately)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10G EnCor® Probe</td>
<td>40% Larger</td>
</tr>
<tr>
<td>9G ATEC/Eviva</td>
<td>60% Larger</td>
</tr>
<tr>
<td>12G EnCor® Probe</td>
<td>35% Larger</td>
</tr>
<tr>
<td>12G ATEC/Eviva</td>
<td>150% Larger</td>
</tr>
<tr>
<td>7G EnCor® Probe</td>
<td></td>
</tr>
<tr>
<td>8G Mammotome™</td>
<td></td>
</tr>
<tr>
<td>10G EnCor® Probe</td>
<td></td>
</tr>
<tr>
<td>11G Mammotome™</td>
<td></td>
</tr>
</tbody>
</table>

*Tolerances percentage 17% calculated from data collected on “medium” gauge devices. Data on file.
†See Study Description and Disclosures on last page.
EnCor EnSpire® Breast Biopsy System – The first smart breast biopsy system.

Only the EnCor EnSpire® Breast Biopsy System’s intelligent design enables you to adapt in real time to challenging lesions while in the breast – potentially avoiding the need for reinsertion.

- In-breast adaptability
- Pre-programmed sampling
- Real-time, visual confirmation of needle orientation
- Half sample option – eliminates need for specialty probes
- Designed for use with MRI, stereotactic ultrasound imaging

With a large, intuitive touch screen interface, the EnCor EnSpire® Breast Biopsy System provides visualization of needle activity and easy access to procedure options.
The compact ENCOR ULTRA™ Breast Biopsy System is easy to place within your workflow – with or without its space-saving procedure tray.

**ENCOR ULTRA™ Breast Biopsy System – Performance on a different scale.**

Only the ENCOR ULTRA™ Breast Biopsy System is designed for ultrasound – powerful enough to deliver the performance you need and small enough to give you the convenience and efficiency you want.

- Fully-powered vacuum unit
- Small footprint
- Quiet operation
- Easy set up
- Lower cost of ownership
Individually, the ENCOR® Breast Biopsy Systems are perfect for your practice; each contributes to efficiency with rapid set up and a 67% reduction in medical waste. But together, the practice efficiencies are even greater and include:

- Common probes to consolidate inventory requirements and simplify ordering.
- Similar operation and set up for streamlined training.
- The convenience of a single point of contact.
INDICATIONS:

For use with the EnCor® and/or affiliate. © Copyright 2015 C. R. Bard, Inc. All Rights Reserved. 0115/4632

Bard, EnCor Enspire and EnCor Ultra are trademarks and/or registered trademarks of C. R. Bard, Inc.

bardbiopsy.com

WARNINGS:

Contraindicated for those patients where there is an increased risk of complications associated with percutaneous removal of tissue samples.

Please consult package insert for more detailed safety information and instructions for use.

POTENTIAL COMPLICATIONS:

To measure the inner diameter of the probes, needles were disassembled to access the cannula containing the sample notch. The inner diameter of the sample notch was measured using pin gauges.

STUDY DESCRIPTION:

Conducted by Bard Biopsy Systems, the study included the EnCor Enspire™ Breast Biopsy System, Hologic ATEC™ System, Hologic EVIVA™ System, and Devicor Mammotome™ System. Five (5) probes for each probe type/gauge size were used to acquire 12 samples each (for a total of 60 samples) in chicken breast.

To measure the inner diameter of the probes, needles were disassembled to access the cannula containing the sample notch. The inner diameter of the sample notch was measured using pin gauges.

STUDY DISCLOSURES: Please note that these values are representative for comparison purposes. Performance in human breast tissue will vary. Different patients/densities and consistency of breast tissue will have a different yield in tissue sample mass. Gauge sizes listed are manufacturer-stated gauge sizes and do not necessarily represent the actual measured gauge size.

“AUSTRIA


BENELUX


CZECH REPUBLIC

Bard Czech Republic s.r.o., Taborska 619, 140 00 Prague, Czech Republic. Tel: +420 242 408650. Fax: +420 242 410 185.

FRANCE

Bard France SAS, Av. Joseph Kessel 164-166, Parcile P14, 79860 Vosins-le-Bret%C3%A9meau, France. Tel: +33 1 3905858. Fax: +33 1 39058589.

GERMANY

C. R. Bard GmbH, Wachausstrasse 6, 76227 Karlsruhe, Germany. Tel: +49 721 94450. Fax: +49 721 9445111.

GREECE

Bard Hellas SA, 22, Alkiviadou St & 72, Vouliagmenis Av, 16675 Glyfada, Greece. Tel: +30 210 9690770. Fax: +30 210 9628810.

ITALY

Bard srl., Via Cina 444, 00144 Roma, Italy. Tel: +39 06 524951. Fax: +39 06 52595852.

NETHERLANDS

C. R. Bard Netherlands Sales B.V., Lorentzbloem 4, 3401 MX Ueselstein, The Netherlands. Tel: +31 (0)88 01 22 500. Fax: +31 (0)88 01 22 501

NORDIC


POLAND

Bard Poland sp. z o.o., ul. Cybernetyk 75, 02-677 Warszawa, Poland. Tel: +48 22 3210930. Fax: +48 22 3210938

SPAIN

Bard de Espana S.A.U., Plaza Europa 41-43, 5a Planta, (Torre Realia), 08018 L’Hospital del Llobregat, Barcelona, Spain. Tel: +34 93 253780. Fax: +34 93 205 82 00.

SWITZERLAND

Bard Medica SA, Steevarasee 64, 8942 Oberrieden/Zürich, Switzerland. Tel: +41 44 7225560. Fax: +41 44 7225370.

UK

Bard Limited, Forest House, Tittag Forest Business Park, Brighton Road, Crawley, West Sussex RH11 9BP, UK. Tel: +44 1293 52955. Fax: +44 1293 552428

EnCor® Product Codes

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>PRODUCT CODE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>EnCor Enspire® Breast Biopsy System</td>
<td>E4230</td>
<td>EnCor Enspire® Vacuum Assisted Breast Biopsy System</td>
</tr>
<tr>
<td>EnCor Enspire® Vacuum and Rinse Tubing Cassette</td>
<td>DS4001</td>
<td>EnCor Enspire® Vacuum and Rinse Tubing Cassette</td>
</tr>
<tr>
<td>EnCor Enspire® Ultrasound and Coaxial Cannula – 10G</td>
<td>DS4002</td>
<td>EnCor Enspire® Vacuum and Rinse Tubing Cassette</td>
</tr>
<tr>
<td>SCCAN01</td>
<td>EnCor Enspire® Vacuum Canister</td>
<td></td>
</tr>
<tr>
<td>EnCor Ultra® Breast Biopsy System</td>
<td>ES230</td>
<td>EnCor Ultra® Breast Biopsy System</td>
</tr>
<tr>
<td>SCCAN02</td>
<td>EnCor Ultra® Vacuum Canister</td>
<td></td>
</tr>
<tr>
<td>Ultrasound/Stereo Probes</td>
<td>ECP0112</td>
<td>EnCor® Biopsy Probe – 12G</td>
</tr>
<tr>
<td>ECP0110G</td>
<td>EnCor® Biopsy Probe – 10G</td>
<td></td>
</tr>
<tr>
<td>ECP017G</td>
<td>EnCor® Biopsy Probe – 7G</td>
<td></td>
</tr>
<tr>
<td>Vertical Stereo Probes</td>
<td>ECP0112GV</td>
<td>EnCor® Biopsy Probe – 12G vertical</td>
</tr>
<tr>
<td>ECP0110GV</td>
<td>EnCor® Biopsy Probe – 10G vertical</td>
<td></td>
</tr>
<tr>
<td>ECP017GV</td>
<td>EnCor® Biopsy Probe – 7G vertical</td>
<td></td>
</tr>
<tr>
<td>Ultrasound Stylus and Coaxial Cannula – 12G</td>
<td>ECST0110G</td>
<td>EnCor® Ultrasound Stylus and Coaxial Cannula – 12G</td>
</tr>
<tr>
<td>ECST0110G</td>
<td>EnCor® Ultrasound Stylus and Coaxial Cannula – 10G</td>
<td></td>
</tr>
<tr>
<td>ECST0107G</td>
<td>EnCor® Ultrasound Stylus and Coaxial Cannula – 7G</td>
<td></td>
</tr>
<tr>
<td>MRI Probes</td>
<td>ECPPR0110G</td>
<td>EnCor® MRI Biopsy Probe – 10G</td>
</tr>
<tr>
<td>ECPPR0112GV</td>
<td>EnCor® MRI Biopsy Probe – 12G</td>
<td></td>
</tr>
<tr>
<td>ECPPR0107G</td>
<td>EnCor® MRI Biopsy Probe – 7G</td>
<td></td>
</tr>
<tr>
<td>MRI Accessories</td>
<td>ECMMINTLOC</td>
<td>EnCor® Introducer Set – 10G</td>
</tr>
<tr>
<td>ECMMINTLOC7G</td>
<td>EnCor® Introducer Set – 7G</td>
<td></td>
</tr>
</tbody>
</table>

EnCor Enspire® and EnCor Ultra® Breast Biopsy Systems

INDICATIONS: The EnCor Enspire® and EnCor Ultra® Breast Biopsy Systems are indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities.

CONTRAINdications: The EnCor Enspire® and EnCor Ultra® Breast Biopsy Systems are contraindicated for those patients where there is an increased risk of complications associated with percutaneous removal of tissue samples.

WARNINGS: The EnCor Enspire® and EnCor Ultra® Breast Biopsy Systems must be properly grounded to ensure patient safety. Use of accessories not compatible with the EnCor Enspire® and EnCor Ultra® Breast Biopsy Systems may create potentially hazardous conditions.

PRECAUTIONS: This equipment should only be used by a physician trained in its indicated use, limitations, and possible complications of percutaneous needle techniques. Patients who may have a bleeding disorder or who are receiving anticoagulant therapy may be at increased risk of complications. As with any biopsy instrument, there is a potential for infection. POTENTIAL COMPLICATIONS: Potential complications are those associated with any percutaneous removal/biopsy technique for tissue collection. Potential complications are limited to the region surrounding the biopsy site and include hematoma, hemorrhage, infection, a non-healing wound, pain and tissue adherence to the biopsy probe while removing it from the breast. Please consult package insert for more detailed safety information and instructions for use.

“’We do about 900 core biopsies a year with EnCor® Breast Biopsy System and there have been no cases that we can’t biopsy because the breast is too dense or the lesion is too firm or sclerotic for us to be able to get our needle through.”

Linda B. Griska, M.D.”