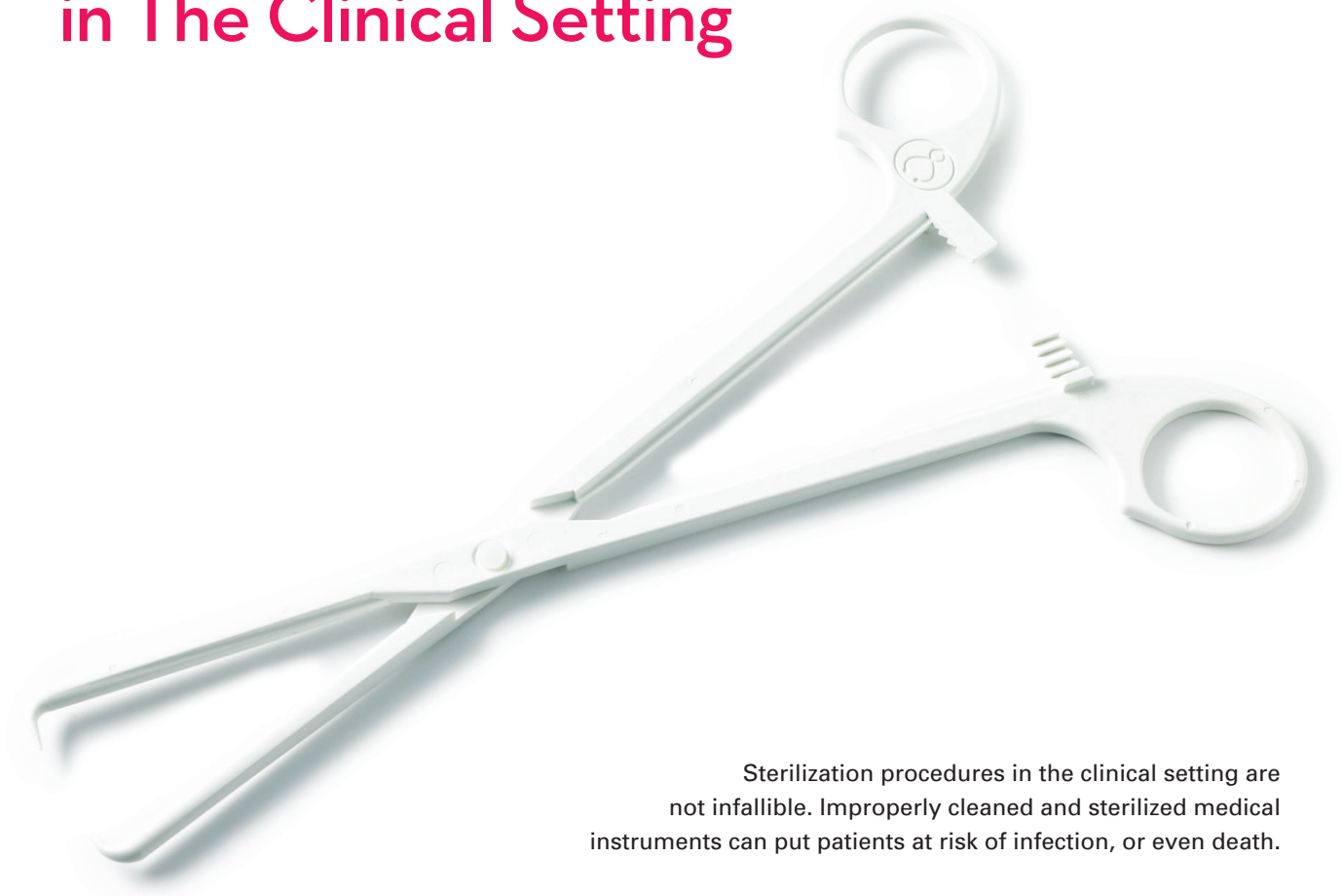


Phillips Plastics Corporation®

INTERFACE

Partnership Creates The
Rx For Increased Safety
and Comfort of Women
in The Clinical Setting



Sterilization procedures in the clinical setting are not infallible. Improperly cleaned and sterilized medical instruments can put patients at risk of infection, or even death.

In fact, the Center for Disease Control (CDC) estimates that there are nearly 1.7 million hospital-acquired infections in U.S. hospitals, resulting in nearly 100,000 deaths annually. These infections cost nearly \$5 billion a year.



“Single-use instruments eliminate the risk of disease transmission to patients and caregivers,” says James Patterson, MD and CEO of GYN Disposables, Inc.

A Man on a Mission

In 2004, Patterson founded GYN Disposables to develop and market single-use medical devices for the treatment of women in the clinical setting. The company’s mission is to provide single-use products with uncompromised performance that are cost-effective for OB/GYN practices.

Single-use medical devices from GYN Disposables offer considerable benefits in safety and comfort. Safety is ensured by avoiding sterilization issues and comfort is increased by advanced instrument design.

The Next-generation Tenaculum

Throughout his 22 years as an OB/GYN, Patterson observed that most of the instruments and materials he used to provide patient care were disposable. Since they were discarded after each use, they were not in need of sterilization within the clinic.

Among the exceptions was the tenaculum. A type of forceps, the tenaculum is a small, sharp-pointed hook, set in a handle and used

for grasping and stabilizing tissue, and for GYN Disposables purposes, the cervix.

“I thought it was strange that no one had ever made a disposable tenaculum. When I set out to do it, I found out why: it was extremely difficult,” Patterson recalls.

Traditional tenaculums are made of stainless steel and have complex designs that are difficult to replicate, affordably. Yet, Patterson persisted to fulfill a tremendous need for single-use tenaculums in the marketplace. In addition, he sought to take an instrument that has been used for decades, and make it better.

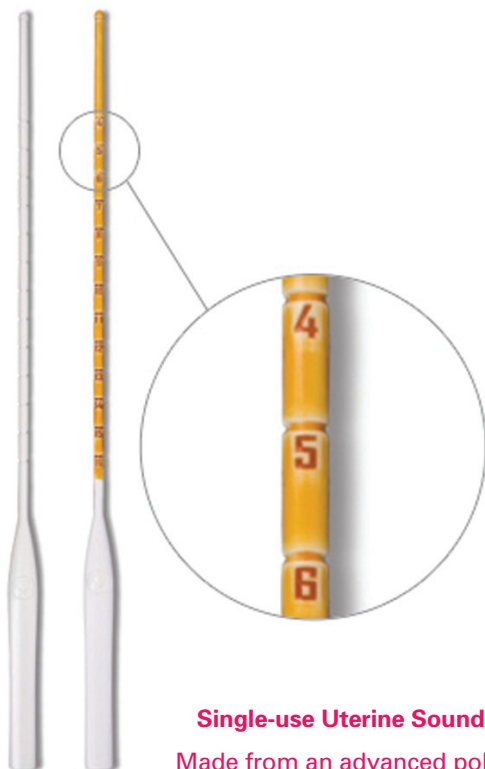
“Tenaculums have been ubiquitous in the OB/GYN practice for decades. This project was my opportunity to design a tenaculum that would be superior to its stainless-steel counterpart,” Patterson says.

The tenaculum would need to be produced in an advanced composite material, with flexible components capable of performing while providing minimal tissue damage.

GYN Disposables and Phillips Plastics

Patterson and Design Engineer Dimitri Protopsaltis partnered to develop the design for GYN Disposables Single-use Tenaculum 356T. Together they evaluated facilities to manufacture the device, and ultimately chose Phillips Plastics.

According to Protopsaltis, Phillips Plastics offered the wide range of manufacturing services and in-depth level of expertise GYN Disposables sought in a manufacturing partner.



Single-use Uterine Sound 906S

Made from an advanced polymer material, the single-use Uterine Sound 906S offers distinct advantages, including ergonomic design for easy handling, easy-to-read markings for fast and precise measurement, and balanced flexibility, with an advanced polymer material that offers the correct amount of pliancy to follow the curve of the cervix and uterus for quick and efficient procedures.

Phillips Plastics worked with GYN Disposables to develop and test device prototypes in different materials. “This step was key to the success of the project, since we couldn’t finalize the design until we understood exactly which material we would use, and how the instrument would perform,” explains Protopsaltis.

Patterson adds, “We enjoyed working with Phillips Plastics on the prototype of the design. Our associates there were professional, and had provided us with valuable input, as well as fast turnaround.”

Single-use Uterine Sound 906S

While working together on the single-use Tenaculum 356T, GYN Disposables and Phillips Plastics collaborated to produce the single-use Uterine Sound 906S.

The single-use Uterine Sound 906S is used for two purposes: 1) to dilate the cervix, and 2) to determine the depth of the uterus.

The sound is latex free, and the centimeters depth markings are easy to read when used with the Povidone-iodine solution.

Both the sound and the tenaculum are sold separately in boxes of 10 and included, along with other instruments and materials, in the following two kits:

- **Single-use IUD Insertion Kit 935K**
An all-inclusive kit that contains everything a medical professional requires to quickly and safely perform an IUD insertion.
- **Single-use Endometrial Biopsy Kit 936K**
An all-inclusive kit that contains everything a medical professional requires to quickly and safely perform an endometrial biopsy.

Single-use Tenaculum 356T

Made from an advanced composite material, the single-use Tenaculum 356T offers distinct advantages over the traditional stainless-steel counterpart. In addition to decreasing the risk of transmission of infectious agents, use of the Tenaculum 356T helps decrease sterilization costs, increase efficiency, and enhance patient comfort. In addition, its composition flexes and travels along the path of least resistance in the cervix, potentially reducing pain and bleeding.



“There are other single-use uterine sounds on the market, but we sought to design one that offered distinct advantages for caregivers’ procedures, including ergonomic design, balanced flexibility, and easy-to-read measurements,” says Patterson.

Full-service for Success

With direction from GYN Disposables, Phillips Plastics helped choose material that would comply with biocompatibility and packaging validations required for GYN Disposables to file an FDA 510K for the Tenaculum 356T.

In addition, Phillips Plastics injection molds, packages and assembles both the Tenaculum 356T and the Uterine Sound 906S on behalf of

GYN Disposables and ships them to a subcontractor for sterilization and kit assembly.

“Phillips Plastics is a great company to work with. They provide expert engineering assistance, and quick response. Our collaboration runs smoothly, and as a result, we’ve created two devices that have been very well received in the marketplace,” says Patterson.