Solutions for Thermo-Ablation with RF medical technologies

March, 2015

Contents

1. About STARmed

Overview

Why STARmed	Solutions for Thermo-Ablation with RF medical technologies
	Suggest solutions for your treatment by RFA
	Being a cornerstone of local ablation treatment
Website	www.STARmed4U.com
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	E-mail : info@starmed4u.com / overseas@starmed4u.com

History

2010

Start Overseas Business with **Italy, Austria, India** etc.

Participate in Various Oncology Exhibition (**ECR, ECIO, CIRSE, APCCVIR**)

2011

Take over Well point RF system from Taewoong Medical.

Start Domestic Business

Start Overseas Business with Singapore and Taiwan

Participate in Various Oncology Exhibition (**WCIO, CIRSE…**)

2012

Expand Overseas Business **Spain, Greece, Netherland, Switzerland, Turkey**

Exhibition Arab Health Exhibition & Congress 2012(**Arab Health**) on January in Dubai, UAE

Start Chinese Business

Participate in Various Oncology Exhibition (**ECIO, CIRSE**…)

Additional Products Approval of **CE on May** - Extension indications

Introduce **Endoscopic Electrodes** to an International Conference **UEGW**

History

2013

Expand Overseas Business
Portugal, Egypt, Belgium

Participate in Various Oncology
Exhibition **(ECIO, CIRSE, UEGW)**

Additional Rigid Products
Approval of KFDA on **May**
(VIVA multi RF generator)

Additional Flexible Products
Approval of CE on **Sep**
(ELRA electrode)

2014

Expand Overseas Business
Participate in Various Academic
Exhibition **(ETA, CIRSE, ACTA,**
DDW, UEGW…)

Additional Rigid Products
Approval of KFDA **on June**
(**Proteus** for Virtual Navigation
System)

Additional Flexible Products
Approval of CE on **June**
(**VIVA combo RF generator**)

Make a Partnership with
Taewoong Medical for
International Sales & Marketing
of **Flexible Products**

Certification

KFDA, KGMP, GIP
Korea Food & Drug Administration

CE (EU)
EN 60601-1:2006
EN 60601-2-2:2009
ISO 13485:2003
ISO 9001-2008
Directive 93/42/EEC

China CFDA
China Food and Drug Administration

Taiwan TFDA
Registration Certificate for Medical Device

Singapore HSA
Registration for Higher Risk Medical Device

Mongolia Certificate
Registration Certificate
for Medical Device

Israel Certificate
Registration Certificate
for Medical Device

Japan MHLW-PMDA
Registration Certificate
for Medical Device

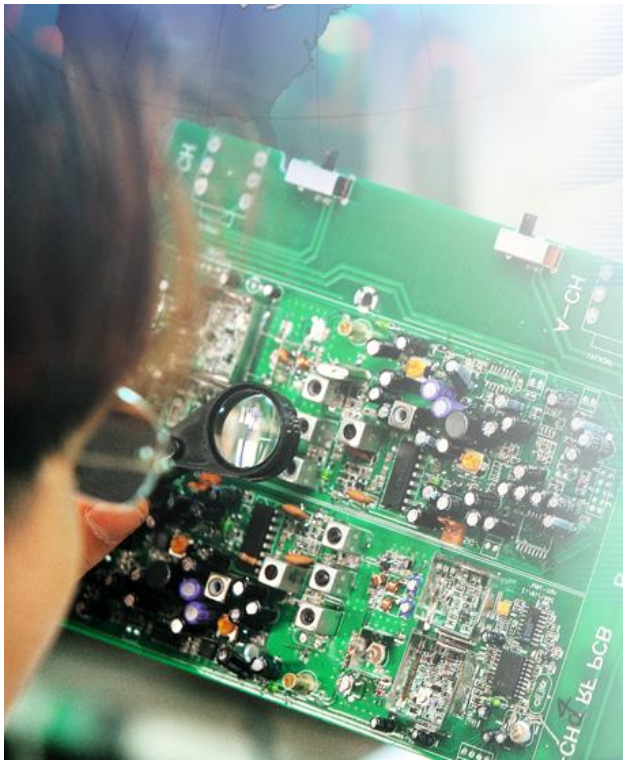
Facilities

- All facilities located in KOREA
- R&D : ex-vivo test Laboratory, equipment & devices, development facilities
- Out Sourcing Partners :

  USA, Japan, Taiwan, China & Korea

R&D manpower

- Equipment : Hardware, Software, Circuit etc.
- Device : Developments, in-vivo, ex-vivo Test, modifications, customizing, etc.
- Out Sourced Consultations : Design, Safety test, etc.



Technologies - Electrodes

Coolant Method

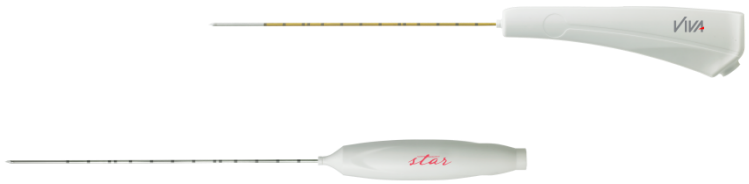
- Enhance Powerful Output by stable impedance

Adjustable Exposure Length Technique

- Single size electrode ablate Various size of Tumors.

Bipolar

- No need Pads



Uni-faced (Thyroid RFA only)

- Half-moon shaped ablation for preventing thermal damage

Create Various Ablation Size

- Smallest(5mm Diameter) – Largest(55mm Diameter)

Flexible electrodes

- Various ablation treatment with working channel

Technologies - Generator

Simple User Interface

- Easy & convenience operation
- Monitoring screen for observation

Minimized Harmonic Frequency

- Less noise by Ultrasound monitor during RFA

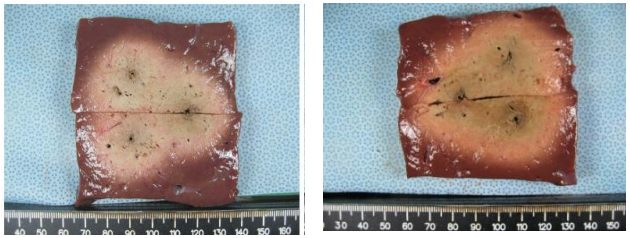
Various modes

- From the inexperienced to the experienced
- Liver RFA(General, Auto, Continuance mode)
- Thyroid RFA(Continuance mode)
- Maximizing RF output efficacy
- Multi-channel output technique(VIVA multi RF generator)

Technologies - Ex-vivo Data

Bovine liver ex-vivo tests

- More than 10,000 cases
- Abundant evidence



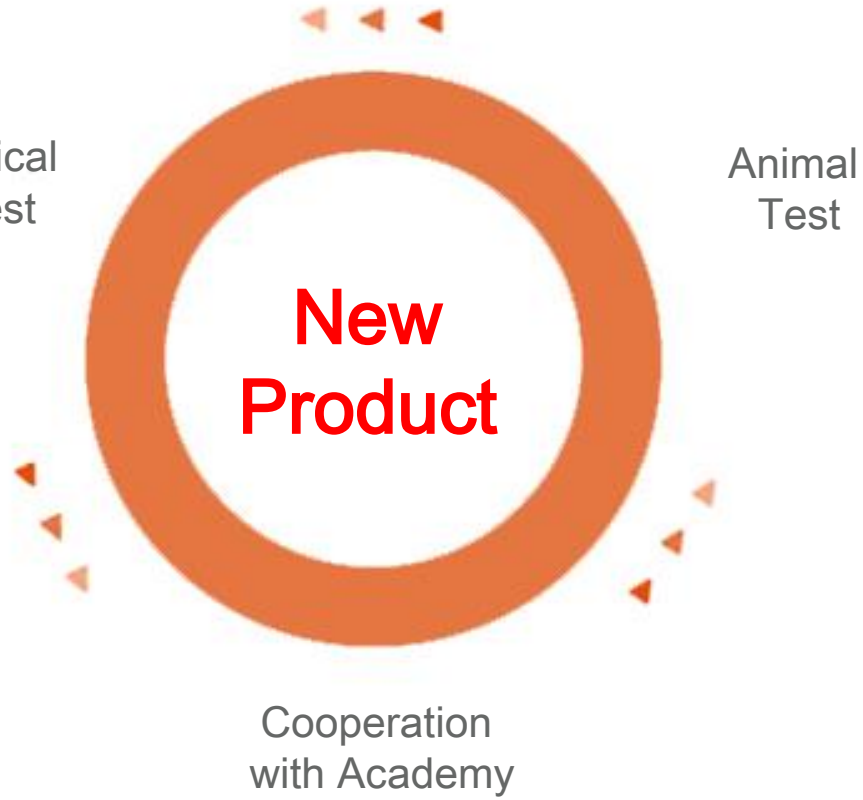
Ex-vivo tests

with Various type of electrodes

- VIVA
- Octopus
- Uni-faced
- Bipolar
- Injectable

- EUSRA
- ELRA

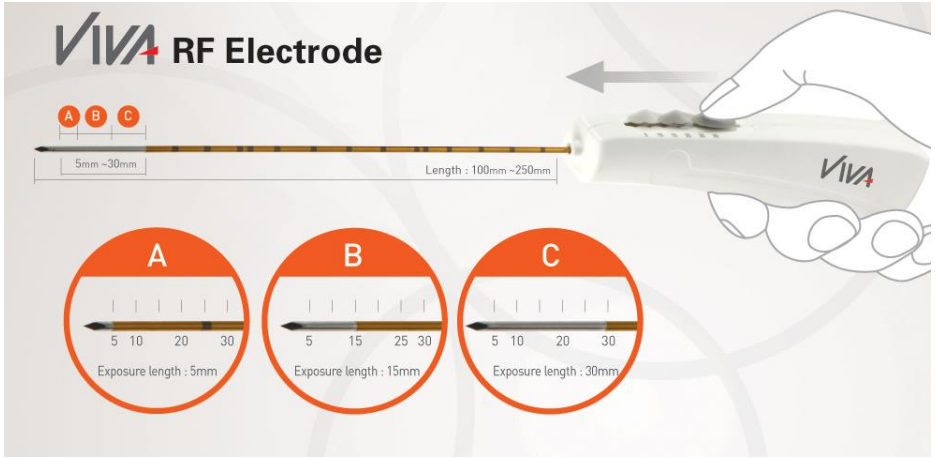
Technologies - In-vivo Data



Products Range - Rigid

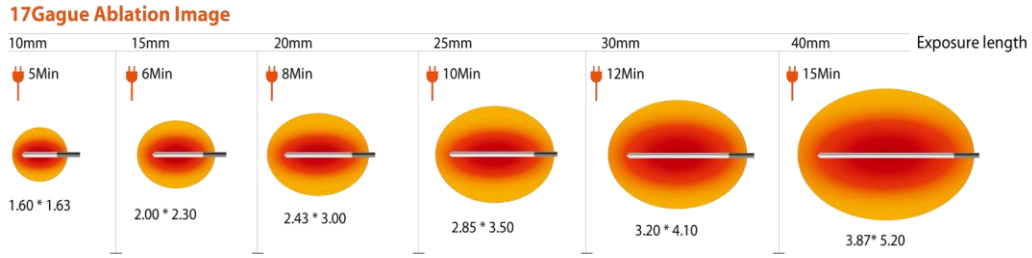
VIVA RF Electrode (monopolar)

- Variable Insulation, Varisized Ablation
- Single Electrode with an Adjustable Active Tip
  for the patients with Multiple Nodules



Products Range - Rigid

VIVA RF Electrode (monopolar)



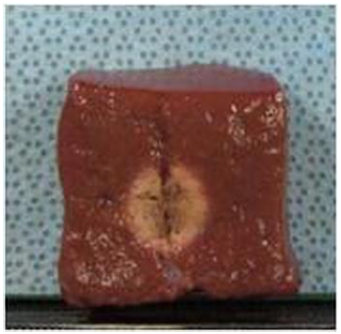
Products Range - Rigid

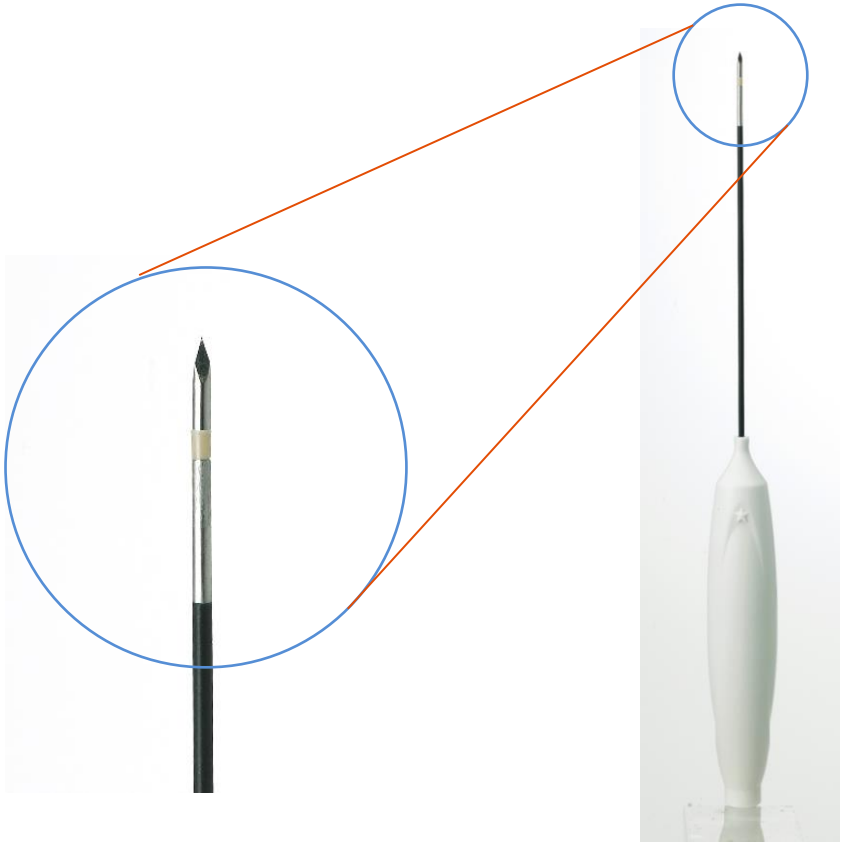
star RF Electrode-Fixed

VIVA, star Fixed, xx30		Competitor, xx30
200watt, 12min		200watt, 12min
	V S	
32.2*40.3(mm)		31.9*40.5(mm)

Products Range - Rigid

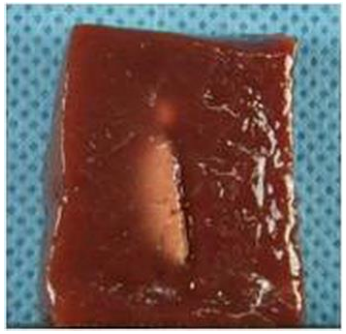
star Bipolar RF Electrode

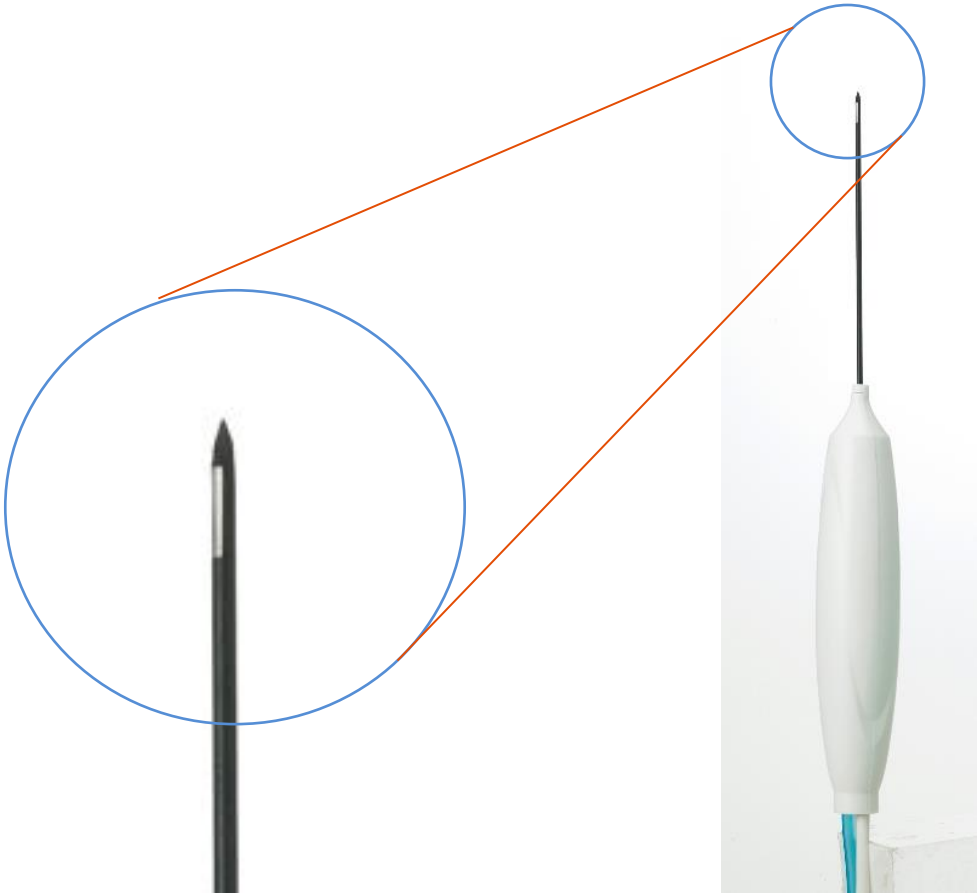
Bipolar, 6:2:10
20watt, 2min

9.7*11.5(mm)



Products Range - Rigid

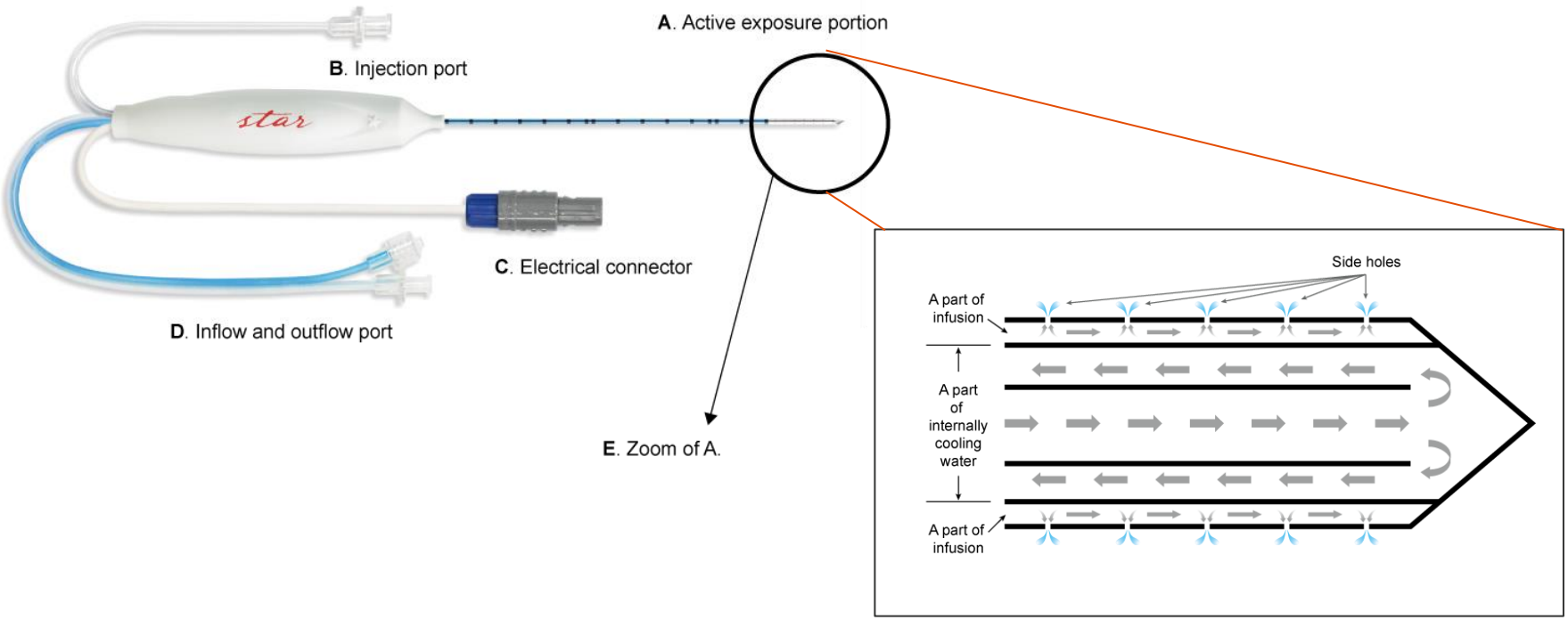
star RF Electrode-Uni_faced

Uni_faced, ∠90
5watt, 6min

9.7*11.5(mm)



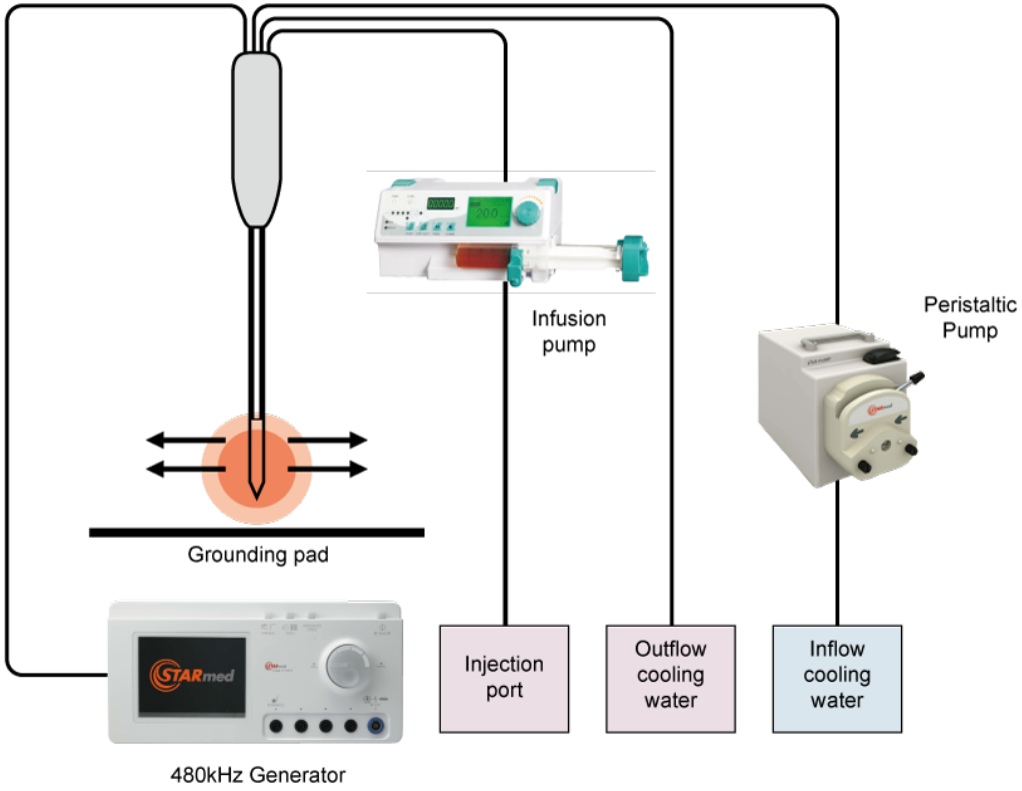
Products Range - Rigid

star Injectable RF Electrode-Injectable



Products Range - Rigid

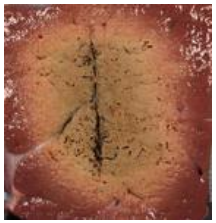
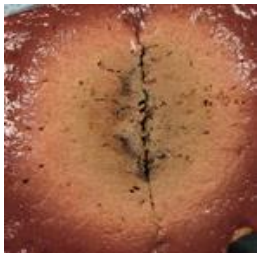
star Injectable RF Electrode-Injectable



Products Range - Rigid

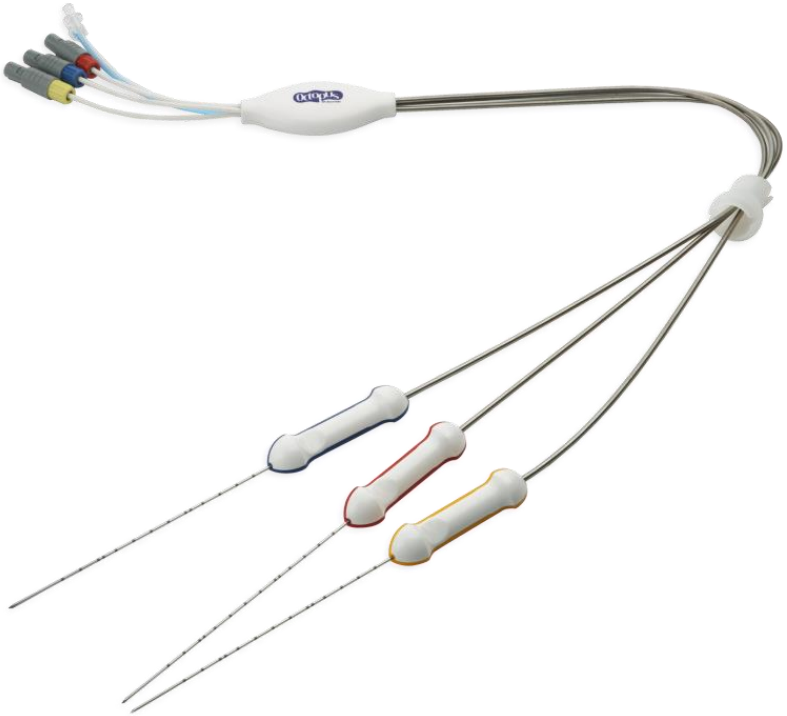
star Injectable RF Electrode-Injectable

- Overcome the limitation of straight single electrode
- Enhance electrical & thermal conduction by liquid injection
- Create larger ablation zone than normal single electrode

star Fixed 17G / 30mm	star Injectable 17G / 30mm	star Injectable 17G / 30mm	star Injectable 15G / 30mm
20watt, 2min	200w, 12min, 0.5cc/m	200w, 15min, 0.5cc/m	200w, 18min, 0.5cc/m
			
9.7*11.5(mm)	36.2 * 44.1(mm)	42.1 * 48.1(mm)	48.3 * 49.5(mm)

Products Range - Rigid

Octopus RF Electrode



Products Range - Rigid

Octopus RF Electrode

- Multi Electrodes for large & Multiple lesions
- Designed to activate three active tips with 200 watts simultaneously or sequentially
- Create larger ablation zone than single electrode

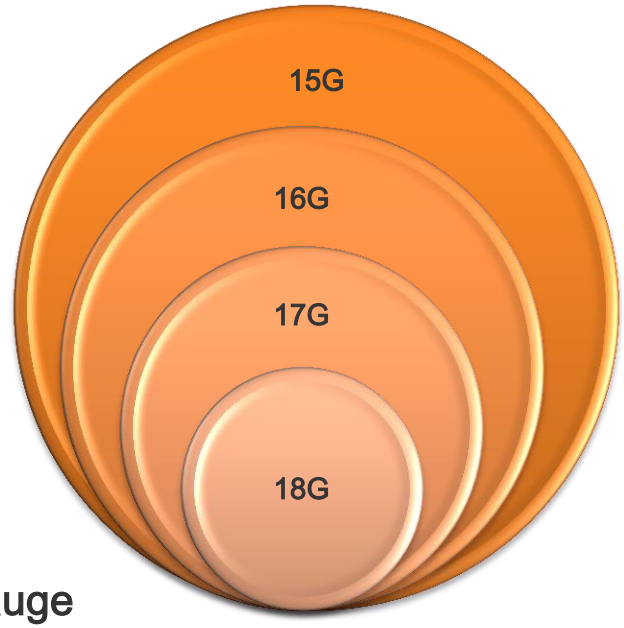
References

- Eun Sun Lee, Jung Min Lee et al. Multiple electrode radiofrequency ablations using Octopus electrodes in animal vivo porcine liver model. Brit J Radiol 2012.
- Eun Sun Lee, Jung Min Lee et al. Evaluation of the In Vivo Efficiency and Safety of Hepatic Radiofrequency Ablation Using a 15-G Octopus® in Pig Liver. Korean J Radiol 2013;14(2):194-201
- Jeong-Hee Yoon, Jung Min Lee et al. Dual Switching Monopolar Radiofrequency Ablation Using a Separable Clustered Electrode: Comparison with Consecutive and Switching Monopolar Modes in Ex Vivo Bovine Livers. Korean J Radiol 2013;14(3):403-411

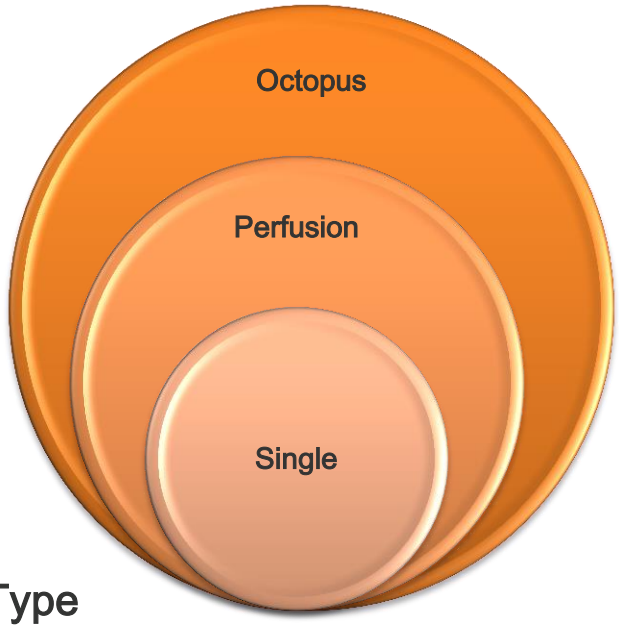
Products Range - Rigid

Octopus RF Electrode

- How to increase Ablation size with Single Electrode?



Gauge

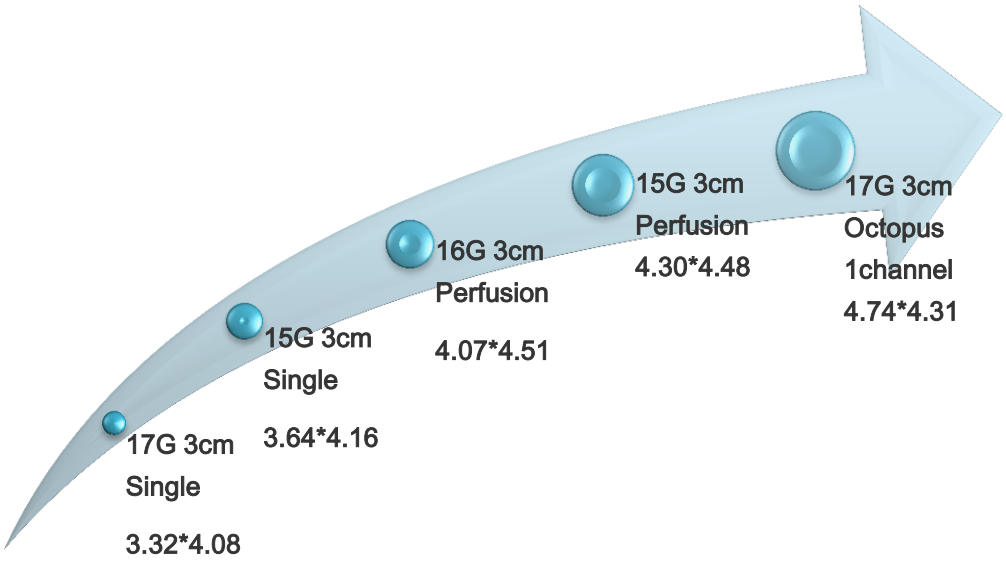


Type

Products Range - Rigid

Octopus RF Electrode

- How to increase Ablation size with Single Electrode?



17G 3cm Octopus
Multi-channel
6.00*5.40

Ex-vivo/in-vivo test result

Products Range - Rigid

VIVA Multi Generator

- Max. 200W (Max. 400W on the Dual Switching Mode)
- 3 different single ablation modes
- 3 different multiple ablation modes

Octopus RF electrode with VIVA multi generator

Original Article | Gastrointestinal Imaging

http://dx.doi.org/10.3348/kjr.2013.14.3.403
pISSN 1229-6929 · eISSN 2005-8330
Korean J Radiol 2013;14(3):403-411

Korean Journal of Radiology
KJR

Dual Switching Monopolar Radiofrequency Ablation Using a Separable Clustered Electrode: Comparison with Consecutive and Switching Monopolar Modes in *Ex Vivo* Bovine Livers

Jeong-Hee Yoon, MD[1], Jeong Min Lee, MD[1,2], Joon Koo Han, MD[1,2], Byung Ihn Choi, MD[1,2]

[1]Department of Radiology and [2]Institute of Radiation Medicine, Seoul National University College of Medicine, Seoul 110-744, Korea

Objective: To compare the *in-vitro* efficiency of dual-switching monopolar (DSM) radiofrequency ablation (RFA) using a separable clustered electrode (Octopus® electrodes) with consecutive monopolar (CM) and switching monopolar (SM) RFA techniques to create an ablative zone in the explanted bovine liver.

Materials and Methods: For DSM-RFA, we used a prototype, three-channel, dual generator RFA Unit and Octopus® electrodes with three, 17 gauge internally cooled electrodes. The RFA Unit allowed simultaneous radiofrequency (RF) energy

2. R & D

Under Development

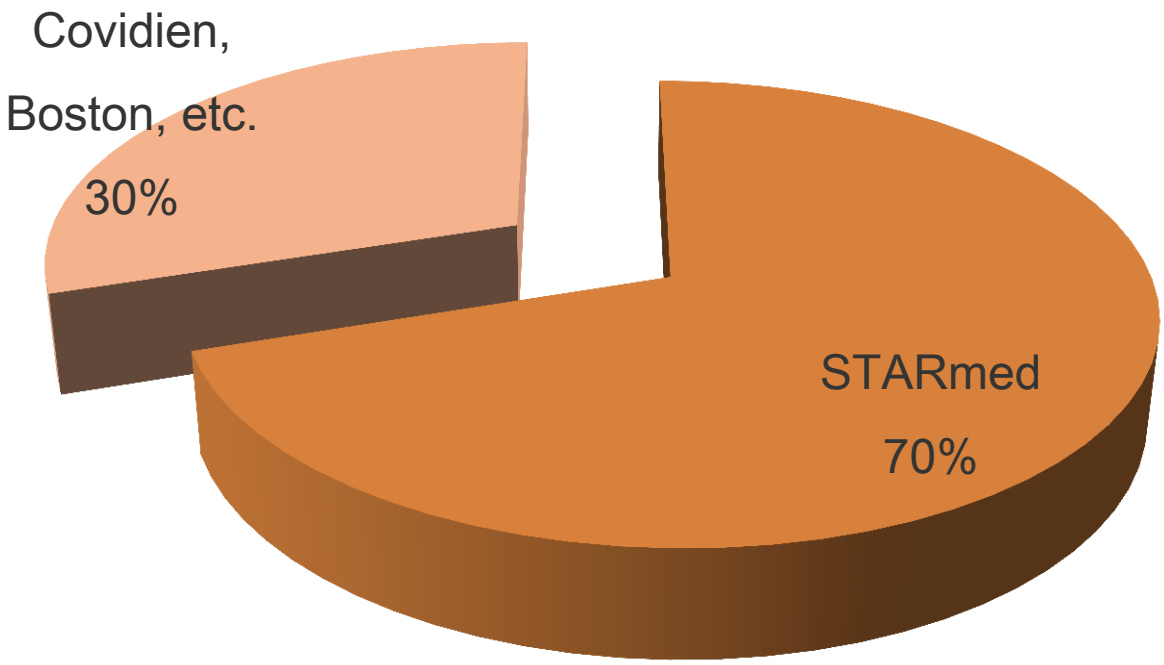
R&D

- Equipment
  - Needle Tracking system (GE Logiq E9)
  - PC interworking program
  - Microwave(MW)
  - Biopsy Tract Ablation

- Electrodes
  - Electrode for G-I system, Endo-biliary system
  - Electrode for Various Indications
  - Electrode for Real-time tissue temperature check

3. Business

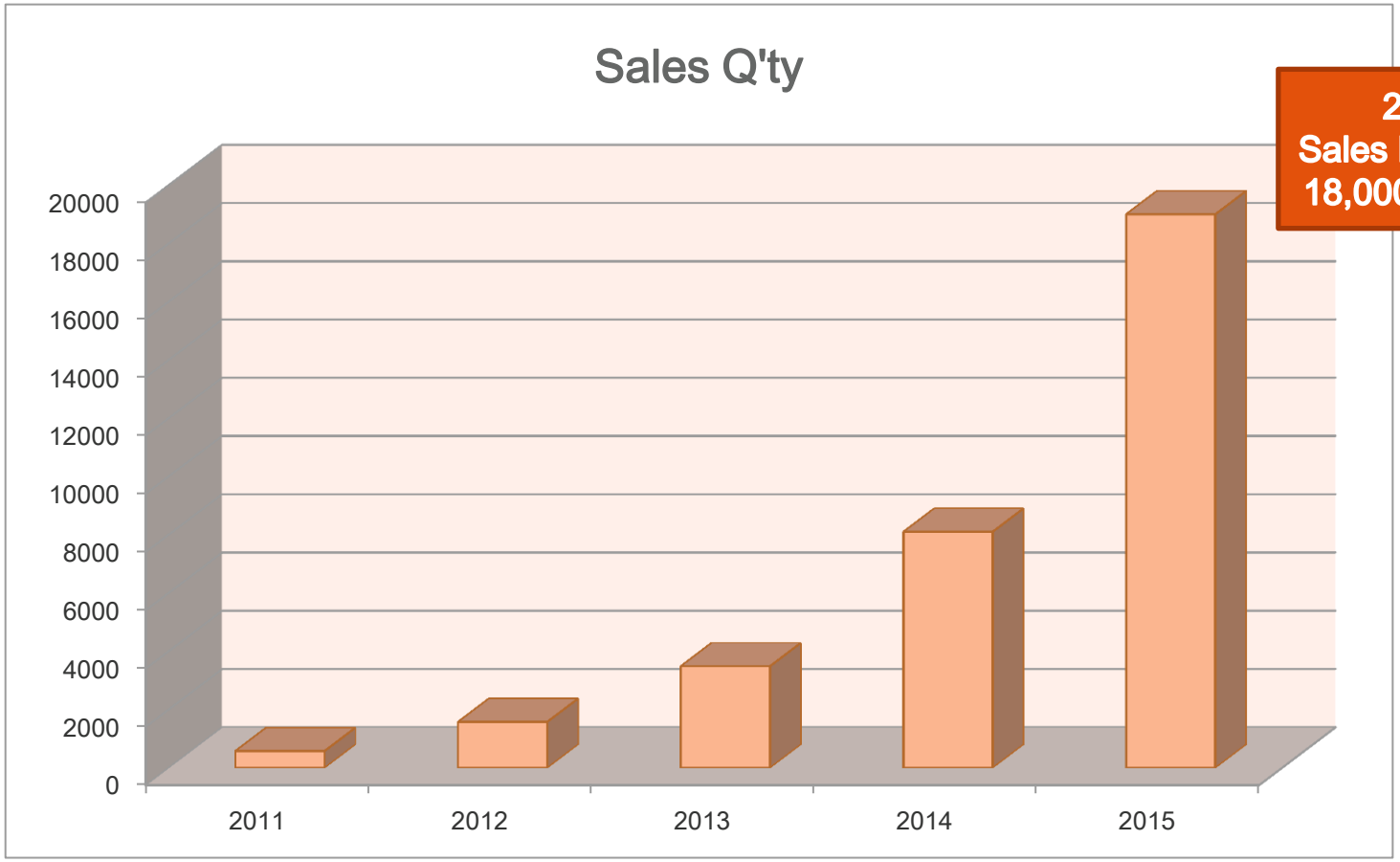
Market Share in Liver RFA



*Total RFA cases of Liver Ca in **2013** : **5,334** cases*
From Health Insurance Review & Assessment Service of Korea

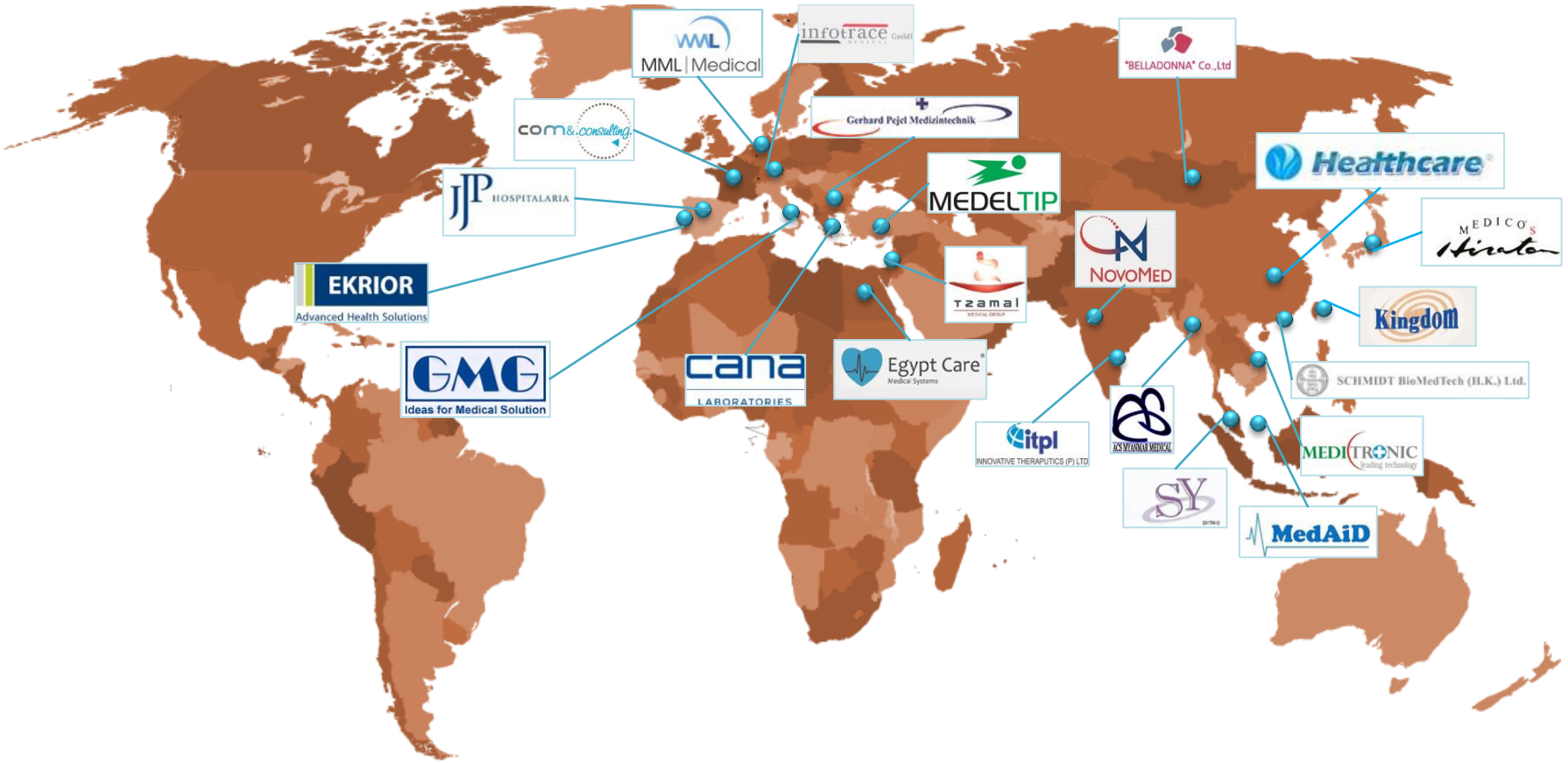
2014

Business



2015 Sales Forecast: 18,000~20,000

Overseas Partners - Rigid



Philosophy

- What is the Philosophy of STARmed?

  Increasing Quality for treating my family

  Sharing Profit under the sense of Humanity

  Improving Patients QOL by our technologies

THANK YOU