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**NOVEL IODINE - BASED ORAL RINSE**

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— { Charles J. Gauntt, Ph.D.  
Biomedical Development Corporation } —

# NOVEL IODINE - BASED ORAL RINSE

Chemistry Liberates I<sub>2</sub>

Removes and kills biofilm

Inactivates endotoxin (LPS)

Effective against gingivitis and plaque

Antimicrobial

No known microbial resistance

Non-sensitizing/Non-irritating/Non-staining

Refreshing taste



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## POVIDONE IODINE VS. BDC RINSE

### Povidone Iodine



- High iodine content
- Bonded to polymer
- Low  $I_2$  per unit iodine
- Staining
- Metallic taste
- Stable

### BDC Oral Rinse



- Low iodine content
- Not bonded to polymer
- High  $I_2$  per unit iodine
- Non-staining
- Refreshing taste
- Stable



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## NOVEL IODINE-BASED ORAL RINSE ONCE A DAY

Average reduction in gingival index:  
**38.4% (16.7% > placebo)**




Average reduction in bleeding index:  
**52.4% (16.4% > placebo)**

{ LDL-C significantly lower in treatment group  
vs. placebo at day 90 but not day 0



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## NOVEL IODINE-BASED ORAL RINSE ONCE A DAY

-  NO irritation / alterations in taste perception
-  NO treatment related adverse events
-  NO significant differences in thyroid function tests



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## NOVEL IODINE-BASED ORAL RINSE

### Continued Studies

A **6 month** clinical study is underway at the  
**CENTER FOR ORAL HEALTH RESEARCH**  
*at the University of Kentucky*



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## NOVEL IODINE-BASED ORAL RINSE EFFECTIVE AGAINST ORAL PATHOGENS

- Actinomyces naeslundii
- Actinomyces actinomycetemcomitans
- Lactobacillus paracasei
- Porphyromonas gingivalis
- Porphyromonas intermedia
- Streptococcus mutans
- Streptococcus oralis
- Treponema denticola



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## NOVEL IODINE-BASED ORAL RINSE BROAD SPECTRUM ANTIMICROBIAL

Property	Assay	Organism	Results
Hard Surface Disinfectant	AOAC	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Salmonella choleraesuis</i>	100% kill of all bacterial species
Fungicidal	AOAC	<i>T. mentagrophytes</i>	100% kill of fungi
Yeast Biofilm ✓	XTT Reduction Assay	<i>C. albicans</i> and <i>C. glabrata</i> biofilm	Dose Response, up to 100% kill
Virucidal	AOAC	Herpes Simplex Type 1	>99.99% reduction in less than 15 minutes
Virucidal	AOAC	Polio Virus Type 1	>99.9% reduction in less than 15 minutes
Tuberculocidal	AOAC	<i>Mycobacterium bovis</i> BGC	>99.999% reduction
Biofilm ✓	Center for Biofilm Engineering	Mixed Biofilm	>99.999% kill
Endotoxin ✓	Center for Biofilm Engineering	Mixed Gram-negative bacteria	62 to 68% reduction

\* AOAC: Association of Official Analytical Chemists International

\*\* Our iodine-based waterline cleaner (iCLEAN™ Waterlines, formerly Dentacide) was successfully used to clean and freshen the dental water lines at the UTHSC-SA College of Dentistry



## NOVEL IODINE-BASED ORAL RINSE TOXICITY AND BIOCOMPATIBILITY

Study	Results
• ISO Agar Diffusion Cytotoxicity Test	Acceptable
• Acute Inhalation Toxicity	Non toxic/Non irritating
• Primary Eye Irritation	Non toxic/Non irritating
• Primary Skin Irritation	Non toxic/Non irritating
• Acute Dermal Toxicity	Non toxic/Non irritating
• Acute Oral Toxicity	Non toxic
• Guinea Pig Sensitization	Non-sensitizing
• 30 Day Human Clinical Trial (dose: twice per day)	Safe – no adverse events Transient changes in TSH
• 90 Day Human Clinical Trial (dose: twice per day)	Safe – no adverse events Transient changes in TSH
• <u>90 Day Human Clinical Trial</u> <u>(dose: once per day)</u>	<u>Safe – no adverse events</u> <u>No significant changes in TSH</u>

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